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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,547	11/21/2003	Stephen S. Whitehead	NIH214.001C1	3443

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EXAMINER	
CHEN, STACY BROWN	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,547	WHITEHEAD ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claim 1, 7, 12-17 and 20-24 link(s) inventions I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 7 and 13-17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claim 2, (1, 7, 12-17 and 20-24) drawn to a flavivirus mutant comprising the Δ30 mutation, classified in class 424, subclass 218.1.

II. Claims 3 and 8, (1, 7, 12-17 and 20-24) drawn to a dengue virus type 1 flavivirus mutant, classified in class 424, subclass 218.1.

III. Claims 4 and 9, (1, 7, 12-17 and 20-24) drawn to a dengue virus type 2 flavivirus mutant, classified in class 424, subclass 218.1.

IV. Claims 5 and 10, (1, 7, 12-17 and 20-24) drawn to a dengue virus type 3 flavivirus mutant, classified in class 424, subclass 218.1.

V. Claims 6 and 11, (1, 7, 12-17 and 20-24) drawn to a dengue virus type 4 flavivirus mutant, classified in class 424, subclass 218.1.

(end of linking claim groupings)

VI. Claims 18-19, drawn to a method of producing neutralizing antibodies, classified in class 435, subclass 4. Applicant must elect one mutant embodiment for search and examination outlined above. For example, if Applicant elects the instant Group (Group VI), Applicant must also elect one mutant for use in the method as described in Groups I-V.

VII. Claims 25 and 26, drawn to cDNA and RNA, classified in class 536, subclass 23.1. Applicant must elect one mutant embodiment for search and examination outlined above. For example, if Applicant elects the instant Group (Group VII), Applicant must also elect one mutant as described in Groups I-V.

VIII. Claims 27-28, drawn to a method of making a mutant flavivirus, classified in class 435, subclass 69.1. Applicant must elect one mutant embodiment for search and examination outlined above. For example, if Applicant elects the instant Group (Group VIII), Applicant must also elect one mutant to be made in the method as described in Groups I-V.

IX. Claims 29 and 32, drawn to a method of identifying a mutation that restricts replication in human liver cells, classified in class 435, subclass 4.

X. Claim 30 and 32, drawn to a method of identifying a mutation that promotes growth in Vero cells, classified in class 435, subclass 4.

XI. Claim 31, drawn to a method of assembling a menu of mutations for use in fine-tuning the attenuation and growth characteristics of recombinant dengue viruses, classified in class 435, subclass 4.

Further restriction is required from claim 1 (included in Groups I-VIII). Applicant must elect one mutation from Tables 1-37 for search and examination. This restriction requirement between mutations is required because the mutations are different, requiring separate searches. A search for more than one mutation would be a serious burden on the Office, as the mutations are not identical.

2. The inventions I-XI are distinct, each from the other because of the following reasons:

a) Inventions I-V are related by being flavivirus mutants. However, they are distinct mutants because their respective mutations differ (Tables 1-37), and the backbone virus differs (dengue 1, 2, 3, 4). A search of the literature for each virus with each mutation would be a serious burden on the Office. Further, a search for one virus with one mutation would not reveal other viruses with the same mutation, or different mutations.

b) Inventions (I-V) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the mutant viruses can be used to detect antibodies on a column.

c) Inventions (I-V) and VII are distinct products. The viruses and cDNA/RNA that correspond/encode the viruses are distinct products. The chemical/structural features of cDNA/RNA and whole viruses are different. Nucleic acids encode amino acids, which in turn form polypeptide and protein structures that are arranged and processed to become a virus. A search of the literature for a virus is not commensurate in scope with a search for nucleic acid that encodes the virus. Art that speaks to the mutant virus is not expected to disclose a sequence. Therefore, a search for both the nucleic acid and virus would be a serious burden.

d) Inventions (I-V) and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the virus can be made by subjecting wild type viruses to culture conditions that result in the selection of various mutations that have the claimed phenotypes.

e) Inventions (I-V) and (IX-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The method protocols do not require the mutant viruses of Groups I-V.

f) Inventions VII and VIII are related as product and process of use. The product, nucleic acid encoding a mutant virus, can be used to generate or isolate anti-DNA antibodies.

g) Inventions VI and VIII are distinct methods that do not share method steps. The methods of inducing neutralizing antibodies and making a mutant flavivirus do not require each other for operation.

h) Inventions (VI-VIII) and (IX-XI) are drawn to unrelated inventions. The methods of Groups IX-XI do not require the methods and nucleic acid of Groups VI-VIII.

i) Inventions IX-XI are all distinct methods of determining mutations useful for different purposes. The method of Group IX identifies mutations that restrict replication in human liver cells, while the method of Group X identifies a mutation that promotes growth in Vero cells. The method of Group XI assembles a menu of mutations that cause attenuation and growth characteristics. These methods are drawn to identifying mutations that cause different phenotypes. A search of the literature for mutations that restrict virus replication in human liver cells is not likely to also reveal the identification of mutations that promote growth in Vero cells.

Because these inventions are distinct for the reasons given above and the literature search required for one Group is either not required or not co-extensive for any other Group and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
July 26, 2005